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User manual

apneABP

combined ambulatory blood pressure, pulse oximeter and activity monitor with CardioVisions software

(from version 1.18)

Important information on apneABP systems. Please, read carefully.

	This symbol on a Meditech recorder is a warning that you should read the accompanying documentation (this manual).
Meditech  	apneABP combined ambulatory blood pressure and pulse oximeter monitors and CardioVisions software are manufactured and developed by Meditech Ltd. All title and copyrights in and to the CardioVisions software, the accompanying electronic and printed materials and any copies of the CardioVisions software are owned by Meditech Ltd. The CardioVisions software is protected by copyright laws and international treaty provisions. For details please read the software license agreement. Contact details: Meditech Ltd. 1184 Budapest, Mikszáth Kálmán utca 24., Hungary Tel.: (1) 280 8232, (1) 280 8233 Fax: (1) 282 9388 Mail: meditech@meditech.eu Web: www.meditech.eu Contact us for further product and service information. Meditech Ltd. maintains a quality assurance system certified according to ISO 9001:2008 and ISO 13485:2003. Notified body: SGS Yarsley Unit 202b, Worle Parkway, Weston-super-Mare, BS22 0WA Fax: +44 1934 522 137 Web: www.sgs.com
!	Always consult a physician for the interpretation of the measurements. Note that any blood pressure recording and pulse oximeter signal may be affected by the body position, the physiological condition of the patient, and other factors.
REF **SP1**	Device type. (SP1 = apneABP)
CE 0120	Each device complies with the requirements of the EU Medical Devices Directive. 0120 is the identifier of Notified Body (SGS Yarsley).
MDD IIa	MDD classification IIa. EMC class B. EMC group 1.
	apneABP is internally powered type CF devices. Protection vs. ingress of water: none. Mode of operation: continuous. The device is not protected against defibrillators or other high frequency surgical equipments.

SN ***YYYYSP1nnnnnnnn***	The first four digits of the serial number of a recorder (YYYY) show the year of production, followed by the three characters of the model's identification (SP1), and a eight-digit identification number. For example: 2012SP112345678
	This symbol shows that according to regulations the monitors should be handled as electronic waste during rollout.
	Blood pressure measurements determined with apneABP recorders are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard for Electronic or Automated Sphygmomanometers. The device fulfills the requirements of the British Hypertension Society Validation Protocol for Automated Blood Pressure Measuring Devices.
!	No user serviceable parts inside. Meditech recorders contain high complexity electronic and fine mechanical components. If you have any problems, please contact your qualified service personnel.
	Date of production. The first four digits of the serial number of a recorder show the year of production
	The device operates with direct current.

ID:SP1L20130503_en

1. Recommended use of combined ambulatory blood pressure and pulse oximeter monitors

Indications for ambulatory blood pressure monitoring

The following indications are listed in the European Society of Hypertension recommendations for ambulatory blood pressure measurement, 2003.

- Suspected white-coat hypertension
- Suspected nocturnal hypertension
- To establish dipper status
- Resistant hypertension
- Elderly patient
- As a guide to antihypertensive drug treatment
- Type 1 diabetes
- Hypertension of pregnancy
- Evaluation of hypotension
- Autonomic failure

Indications for pulse oximeter monitoring

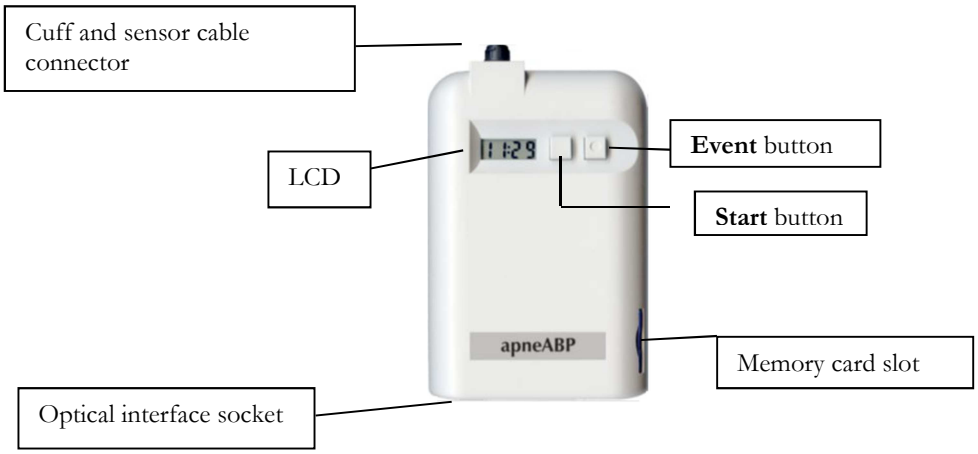
- Cardiovascular problems
- Lung disease (in case of diminution of the oxygen absorbing capacity of the lungs)
- Sleep-related respiratory disorders: diagnosis of apnea or hypopnea

Contraindications

- Non-cooperative patients, unconscious or otherwise incapable patients
- Patients requiring urgency/emergency cardiac care
- Patients with coagulation disturbances
- Patients with serious mobility or other impairments without supervision
- Children without supervision, or children younger than 8 years
- Though the blood pressure measurement algorithm used in the monitors has been found to function properly on patients with atrial fibrillation or other common arrhythmias, the oscillometric blood pressure measurement method is generally recommended for use only with special caution in patients with arrhythmias, Parkinson's disease or other diseases with tremor.

2. Devices

apneABP is a silent, PC-based combined ambulatory blood pressure, pulse oximeter and activity monitor, which can be programmed for even 27 hours. 300 measurements can be made by a battery set, while the device itself can store 600 measurements.



The patient can start extra measurement, indicate events or switch between day and night modes by pressing a device button. apneABP operates with Meditech normal, small and large cuffs. For the pulse oximeter monitoring four types of Meditech sensors are available: adult, pediatric, neonatal and ear sensor. Data are stored on a standard SD HC/MMC memory card, you will need a card reader to transfer the recorded data to your computer. You can find the memory card slot on the right side of the device. Operation is ensured by 4 AA accumulators. The state of the batteries can be checked by the voltage display function. The device can be connected to any standard PC with its optical interface cable.

3. Accessories

Set (delivery either in plastic case or carton box)
1* apneABP device
1*memory card
1* USB interface cable
1* pouch with shoulder and waist straps
1* normal size cuff
1*adult pulse oximeter sensor
1* battery charger with two sets of rechargeable batteries
1* CD with the latest software and manual
1* quality certificate

Recorder package (delivery in a carton box)
1* apneABP device
1* memory card
1* pouch with shoulder and waist straps
1* normal size cuff
1* adult pulse oximeter sensor
1* quality certificate

Accessories may vary from place to place.

4. Using the buttons

On the front side of the device there is the unmarked START and the EVENT button, which is marked by a circle**.** Each button press is accompanied by a short beeping sound.

Cancel a blood pressure measurement
The patient can interrupt a blood pressure measurement by pressing a button at any time while the cuff is inflated. This will result in immediate fast cuff deflation.

Manual blood pressure measurement
If it seems necessary, the patient can start an additional, manual blood pressure measurement by pressing the START button shortly (less than 5 seconds). Results with a manual measurement marker will be stored in the memory of the device. Typical causes for this use: dizziness, pain (angina pectoris or headache), palpitation.

LCD check
Press and hold the START button to light up all segments of the LCD to check if they all work correctly.

Battery voltage check
Press and hold the START button for more than 5 seconds to display voltage on the LCD (e.g. 2_64 is equal to 2,64V). After checking the voltage, release the button. The unit will then return to display time. The voltage for fully charged accumulators should be over 5.1V and for fresh alkaline batteries over 6.1V.

Switching the device off and on
apneABP has no switch off or switch on button. The monitor carries out the examinations according to the preset program.

Set a patient event marker
The patient can mark any event without starting a manual blood pressure measurement by pressing the EVENT button briefly. Typical cause for this use is taking medicine. The patient should be instructed to record the reason for setting an event marker in a diary.

Switch between active and passive blood pressure measurement frequency
If this function is enabled during the programming of the monitor, the patient can manually shift the measurement frequency period (day or night) by pressing the EVENT button at least for 5 seconds.

5. Display

The LCD display shows important status information, the processes and the results of individual readings. The most important displays are listed here, in addition to these, a lot of extraordinary situations and errors have their own code displayed on the LCD. These codes, stored together with recorded data, will be listed in the device memory and can be displayed by the software. Information displayed on each device:

	Normal status: time is displayed		Pulse rate value of just completed measurements (beats/minute)
	Blood pressure measurement is initiated (mmHg)		Event marker set during a button push.
	Pumping for measurement, current pressure is displayed (mmHg)		Deflation during measurement, current pressure is displayed (mmHg)
	Battery voltage display (5,13V).		Low battery voltage (three dots below)
	Systolic value of just completed measurement (mmHg)		Diastolic value of just completed measurement (mmHg)
	Communication with a personal computer		Blood pressure measurement is initiated (kPa)
	Pumping for measurement, current pressure is displayed (kPa)		Deflation during measurement, current pressure displayed (kPa)
	LCD check: all segments are displayed.		Rectangle blinking: measurement in progress synchronized with the pulse(kPa)
	Systolic value of a just completed measurement (kPa)		Diastolic value of a just completed measurement (kPa)
	Rectangle blinking: measurement in progress synchronized with the pulse(mmHg)		The blood pressure measurement is cancelled by pressing a button.
	Error code display		SpO_2 error code display

6. Technical parameters

Power supply
4 AA rechargeable NiCd or NiMH batteries or 4 AA alkaline batteries
Display
liquid-crystal
Data storage
Removable flash memory card Supported memory card types: MMC, SD, SD HC
Data transfer
Optical interface, a card reader is necessary for receiving data
Operating environment
Device temperature
10-45 °C
Cuff and pulse oximeter temperature
10-40°C
humidity
relative 10-90%, non-condensing
atmospheric pressure
83-103 kPa
Storage and shipping conditions
temperature
-20 - 50 °C
humidity
relative 10-95%, non-condensing
Size
82*124*33,5 mm
Weight (batteries included)
350g
Blood pressure measurement method
oscillometric
Blood pressure maximum storage
Minimum 400 programmed measurements, additional measurements and event markers
Measurement range
blood pressure: 30-260 mmHg (4-35 kPa)
pulse: 40-200 beat/minute
Passive accuracy
+/- 3mmHg (0,4 kPa) or +/- 2% of measured value (stability: 2 years)
Blood pressure measurement accuracy
algorithm validated to BHS and AAMI protocol
Blood pressure curve sampling rate
100Hz
Pressure sensor
piezo resistive
Inflation
automatically controlled pump
Safety
maximum inflation 300 mmHg; independent safety release valve
Deflation and rapid air release
automatic pressure release valve
Blood oxygen saturation sampling and measurement range
4-beat-average, 0-100 %
Blood oxygen measurement accuracy
+/- 3 % (70-100 % SpO_2)

Plethysmograph sampling and measurement range
75Hz, automatic sensitivity setting
Actigraphy
2-axis polysilicon accelerometer
Actigraphy measurement range, sampling and sensitivity
+/- 1,7g min., 10Hz, better than 0,01g

Please note that the device may not meet its performance specifications if stored or used outside the specified environmental conditions.

7. Care and maintenance

Protection and cleaning

The device is not specially protected against spills or ingression of water or other liquids. Do not immerse the recorder in water or any cleaning fluid and protect it from spills and splashes. Do not expose it to heavy rain or steam and do not wear it in wet environment e.g.: shower, bath or swimming pool. In case of minor effects of wet environment, wipe off water drops with a dry cloth. Keep the recorder in a normal dry room for at least one hour before use if condensation is suspected. In case of ingress of water in the recorder, remove the sensor and the batteries from the unit, and refer the unit to authorized service. Never place a recorder unit in a disinfecting or sterilizing machine! A recommended means of cleaning is to wipe the recorder with a disinfectant cleaning tissue. Alternatively, wipe with a slightly damp cloth then dry it with an antistatic tissue. Do not expose recorders to extreme heat or radiation, including long exposure to direct strong sunlight.

Cleaning and disinfecting of the pulse oximeter:
For cleaning use a clean, soft cloth to wipe the sensor with 70% isopropyl alcohol. Do not use undiluted bleach (5%-5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because it may result in permanent damage.
To clean and disinfect the sensor:

1. Damp a soft, clean tissue with isopropyl alcohol. Wring the tissue to extract excess isopropyl alcohol and wipe the sensor and the cable.
2. Dry the sensor and cable with a soft, clean tissue.

Caution: Do not sterilize by irradiation, steam or ethylene oxide. Such sterilization may damage the sensor.

Cleaning of the cuff:

1. Remove the bladder.
2. Wash by hand the sleeve with lukewarm water and regular washing liquid suitable for black material. Rinse well.
3. If required, wipe the bladder with a mild cleaning tissue.
4. Allow both bladder and sleeve to air dry.
5. Replace bladder in the sleeve.

Regular checks, warranty, service

Verification of the pressure measurement accuracy is recommended biannually. All the devices are covered by a two-year warranty under certain warranty conditions (see chapter *Meditech product warranty conditions).* This warranty does not cover any malfunction or defects arising from improper use, the use of inadequate accessories, accident, theft, or use of the device outside

operating environmental specifications or intended measurement range. Removing the closing label from the back side of the device voids this warranty. There are no user serviceable parts inside the Meditech recorder; it contains high complexity electronic and fine mechanical components. If you have any problems, please refer the recorder to qualified service personnel. All consequences of improper servicing are the sole responsibility of the user. Contact Meditech or your distributor for more service information.

Roll-out

The recorder includes an internal NiCd coin cell which falls under the category of hazardous waste and should be disposed with proper care. The other parts of the device should be handled as normal electronic waste at roll-out.

8. Safety concerns

WARNING! Due to validation and safety reasons the modification of this equipment is not allowed.

Electric shock hazard protection

The recorder meets the relevant shock hazard protection standards. The device uses four 1.5V AA batteries or four 1.2V rechargeable batteries. These exclude all electric shock hazards, even in the unlikely case of multiple device errors. According to electric shock hazard protection standards the applied parts (pulse oximeter sensor, cuff) are categorized in class CF.
Many personal computers do not meet shock hazard protection standards or strict safety regulations applicable to medical devices. Therefore, during the computer-based use of Meditech recorders, keep at least a 2 meter distance between the patient and the computer. This is the required minimum safety distance. The recorder communicates using a standard 3-meter-long plastic optical cable which allows the required safety distance. The plastic optical cable ensures perfect electric separation and reduces the effects of external electric noise. It does not conduct electricity.

Biocompatibility

To avoid infection risks, and for general hygienic reasons, the device, cuff and tubing should never contact the patient's skin directly.
The surface of the sensor that contacts the patient’s skin complies with ISO 10993 standard.

Hazardous materials

Used batteries qualify as hazardous waste and should be disposed with care. Meditech recorders do not contain any materials qualified as pharmaceutical substance or tissue of animal origin. They emit no material hazardous to humans.

Risk of incorrect diagnosis

The basic intended use of apneABP is to record blood pressure and pulse rate values and to measure activity and blood oxygen levels. Patients should be informed about rules of cooperative behaviour, proper handling of the recorder used, and expected results of monitoring in advance. The recorders only provide data to support diagnostic decisions of a qualified physician, they do not automatically provide a diagnosis of any kind. During the evaluation of recorded values, possible artefacts due to external disturbances, motion artefacts, and electrical noise should be observed and handled with caution.

9. The use of the monitor

The recorders can be programmed by CardioVisions software installed on a personal computer. Once the pre-programmed time is reached, the recorder starts operating automatically: it continuously stores pulse oximeter and activity data for the whole period and measures blood pressure according to the monitoring plan

Connecting the recorder to the PC

apneABP is equipped with a connector slot for a special optoelectronic communication cable. In case of this recorder, the computer-end of the interface cable has to be properly plugged into a corresponding socket on the computer before inserting its small recorder-end plug into the socket on the recorder for communication between the CardioVisions software and the recorder.

Steps to follow for the first connection:

- Locate a free 9-pin serial port (also called RS232) or USB port (often labelled ) on your computer.
- Take the optoelectronic interface unit with the optical cable out of package.
- Connect the interface unit to the port.

If you have a serial RS232 port on your computer, just plug in the serial optoelectronic interface. If you have a USB port on your computer but you have a serial optoelectronic interface, use a USB-to-serial converter. If you have a USB port on your computer then connect the USB-type optoelectronic interface from Meditech.

- Connect the recorder to the optical cable.

Connect the small optical plug at the free end of the optical cable into the socket on the device matching the red mark on the cable to the red mark on the recorder labels. Insert and push it gently until it clicks in place. Simply pull to remove. Do not pull the cable itself, always handle the plug.

A recorder so connected is ready for communication with the software. The interface unit converts optical signals to electric ones and vice versa. The twin optical cable transfers optical signals between the interface unit and the recorder. The cable is flexible, but it is sensitive to overfolding and to cutting forces. If you fold the optical cable in too small radius, or if a strong cutting force (e.g. by the edge of a drawer) is applied to it, the optical cable may become optically distorted, which might result in communication errors.

In the CardioVisions software, click the **Tools** menu, then the **Options** command, and in the appearing **Options** dialog, select **Communication** on the left. On the right panel, select the required recorder type, then select the **Meditech USB** or the **Serial port** option as appropriate for the interface unit you have connected to the computer. To check communication, connect the recorder (with batteries in it and switched on) to the recorder-end of the optical cable, select the required port or enable the **Auto search com port** checkbox, and click the **Test** button.

Monitoring step by step

Before you begin, you should have the CardioVisions software properly installed and configured on your computer, and then the recorder is ready to be connected.

Programming

1. Inform your patient about the monitoring rules well in advance.
2. Programming:
Start the CardioVisions programme and select apneABP from the device types. Click on Device/Programming device.
3. Enter new patient data or select patient from the database.
4. Create monitoring plan adjusted to the patient's daily routine.
5. Insert four fully charged, AA size batteries into the battery compartment and check their voltage.
6. Connect the recorder to the computer.
7. Send the monitoring plan from the computer to the recorder unit.
8. Apply the cuff and the sensor to the patient with the device placed in the pouch.
9. Give the patient diary to the patient along with detailed instructions about the rules and the use of the device.

In case of apneABP the software enables to write the monitoring plan directly to the memory card, which makes it possible to create the plan in the absence of the devices as well.

Rules of monitoring

- Inform the patient about the goal and expected results of the monitoring. Provide an event diary and inform him or her about the rules to consider.

- Put the device into the pouch. The patient should fit the adjustable straps of the pouch.

- Wearing a thin shirt under the cuff is recommended. It does not influence the accuracy of the blood pressure measurement, but it prevents problems caused by long-time wearing the cuff (sweat, itching, soreness, etc.)

- The cuff should be properly placed on and connected.

- Patients should avoid excess movement during blood pressure measurements. They should hold their arm loose, slightly away from their chest.

- Should the blood pressure measurements cause bloodshot, torpidity or pain in the hand, the cuff should be removed from the arm immediately and disconnected from the recorder. Such occurrence should be reported to the physician latest after the monitoring session.

- The pulse oximeter sensor operates via optical signals, therefore no external substance should remain between the sensor and the body part which contacts the sensor. Factors that may influence measurement values: nail polish, dye or pigmented cream.

- Preferred location for adult patient is the index finger, alternatively it can be placed on the middle finger or ring finger.

- The patient should not remove the recorder even at night. When turning into sleep problems can be avoided by loosening the straps. The recorder does not disturb most patients at night.

- The patient can initiate extra blood pressure measurements with the START button of the recorder (unmarked button). By pressing the EVENT button (marked with a circle) the patient can mark events, e.g. taking medication etc. If necessary, any blood pressure measurement can be interrupted by pressing any of the device buttons.

- Should the batteries run down during a monitoring session, they can simply be replaced. Monitoring will continue and data will not be lost.

- The patient should never measure anybody else's blood pressure or pulse oximeter level with the recorder during a monitoring session.

Monitoring session (typically 24 hours)

10. Remove the unit the cuff and the sensor from the returned patient.
11. Ask for the patient diary and ask the patient for any events, symptoms, observations or complaints.
12. Start the software and select the proper recorder type.
13. Connect the device to the PC and transfer the collected data from the recorder to your database.
In CardioVisions software select apneABP from the device types and click on Device/Read data.
If the device has been programmed from another database, record patient information into the database after reading in data.
14. Analyse the recorded measurement values.
15. Create and print the report.

10. Batteries

apneABP operates either with four 1.5V AA batteries or with four 1.2V AA rechargeable batteries. (Use only standard long-life (alkaline) batteries, or standard NiCd or NiMH rechargeable batteries of the proper size. A 27-hour monitoring session requires at least 1300mAh-batteries. Do not use lithium batteries. Do not mix different battery types, do not mix new and old batteries. Never use batteries of low or unknown quality or pre-used batteries, as they may not cover the power needs of the recorder, and they may damage the recorder, or they may contain acidic electrolytes which may leak and corrode electronic components. Never use batteries damaged in any way. Should the batteries run down during a monitoring session, they can be replaced. Monitoring will continue and data will not be lost. If you do not use the recorder, it is advisable to remove batteries since they may run down due to the constant small power consumption of the integrated circuits of the device. Data in the recorder are not lost even if batteries run down or are removed. Used batteries may fall under the category of hazardous waste and should be disposed of properly.

Important! It is strongly recommended to use freshly charged accumulators or new batteries with each patient so that batteries do not run down during monitoring, even in case of very high blood pressure values and/or a long monitoring session. After inserting batteries in the device, it is advised to check their voltage before programming them. Do not start a new monitoring session with low batteries. The typical voltage for fully charged rechargeable batteries should be

over 5,2V, and for fresh alkaline batteries, over 6V. It is possible to check battery voltage with the START button. (Please check the *Using the buttons* topic for more details.)

Important! If a recorder is not used for a long, three to six-month-period, the in-built backup cell, ensuring the operation of the internal clock, may get discharged. In this case keep freshly charged batteries in the recorder for at least one day; this will recharge the backup cell. It is possible to use the recorder afterwards. If the backup cell is not properly charged, the internal clock may work incorrectly, and the recorder may not start measurements in the due time. In case of being permanently out of use the replacement of the backup cell might be necessary.

Two sets of rechargeable batteries and a charger are by default included in the complete set. Please consider the relevant instructions while recharging the batteries. If you use alkaline batteries, choose high capacity, long-life products to enable reliable operation.
In order to change batteries, take the recorder out of the holder pouch and remove the battery compartment cover on the back-side. Place four properly charged, high capacity AA rechargeable or four new, long-life AA alkaline batteries into the compartment then close the compartment.

11. Cuffs and their application

It is advisable to wear a thin shirt or blouse under the cuff. This does not influence the accuracy of the blood pressure measurements but it prevents possible problems caused by long-time wear (sweating, itching, etc.). Place the cuff on the upper arm so that the rubber tube points towards the patient's shoulder and the bladder is placed above the brachial artery, if possible. Contrary to the usual placement with the tube pointing downwards, the advantage is that the patient can wear a loose jacket over the cuff. Connect the air connector of the cuff into the air connector socket of the device, which you can find on the top of the recorder. Connect the cuff turning it clockwise with slight pressure.

Note: The cuff should be applied as tightly as comfortable for the patient. A too loose application may result in longer or aborted measurements, because the device has to pump even to reach the proper tightness. Longer measurements may cause inconvenience for the patient, and aborted measurements result in less data for evaluation. If the patient removes the cuff for a period during the monitoring session, it should be reapplied with appropriate tightness, with help from another person, if necessary.
Should blood pressure measurements cause bloodshot, torpidity or pain in the hand, the cuff should be removed from the arm and disconnected from the recorder. Such occurrence should be reported to the physician at once but latest after the monitoring session.

The monitors recognize three different cuff sizes. The size to be used should be set during programming of the device. Attention, inappropriate setting of the cuff size may lead to device malfunctioning, which is inconvenient for the patient and may lead to an unsuccessful measurement.

Name	Bladder dimensions	Sleeve dimensions	Arm circumference range[1]
Normal adult	12 x 25 cm	15 x 56 cm	29-38 cm
Small adult	9 x 18 cm	11 x 32 cm	max 32 cm
Large adult	15 x 33 cm	17 x 77 cm	35-46 cm

Take care to avoid blocking the air flow in the tube of the cuff and twisting the tube. Make sure the cuff and its tubing do not cause strangulation or a circulation problem. Should the patient

[1] When properly applied, the end of the sleeve (the one closer to the tube) should fall in the indicated range

experience arm numbness or pain remaining after any blood pressure reading is completed, the cuff should be removed to avoid permanent vascular or neural injury.

The cuff is the component which, by definition of the relevant standard, is protected against a defibrillator discharge. The substitution of a cuff different from that supplied by Meditech might result in measurement error and/or in certain cases it causes damage to the main recorder unit.

12. Sensors and their application

The intended use of non-invasive pulse oximeter sensors is the monitoring of arterial oxygen saturation and pulse rate.

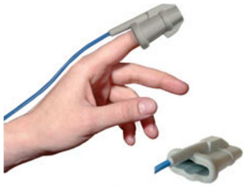
Contraindications: the sensor may be used on the same location for a maximum of 4 hours, if correct application and skin integrity are provided. Since sensor tolerance is influenced by individual skin condition, more frequent change of the sensor location may be necessary.

The use of the sensor:

1. The preferred location of the sensor is the patient's index finger, but alternatively it can be placed on the middle or the ring finger as well.

2. Application

Adult sensor (type reference: 100A): Place the patient's index finger into the rubber sensor until it stops. The sensor cable should point towards the patient's hand.



Neonatal/ Ear sensor (type reference 102A): place the LED and the photo-detector into the neonatal foot strap, and then locate the sensor to the patient's finger in a way that the LED is above the nail and the photo-detector below the fingertip.

If the patient weights less than 4 kilograms, it is advisable to place the sensor on the foot, near to the toes with the sensor cable pointing towards the foot. If this is not possible, you can place the sensor around the patient's palm with the sensor cable pointing towards the hand. The neonatal sensor can be converted to ear sensor the following way: Place the LED and the photo-detector into the clip in a way that the sensor cables are paralleled to each other and they are adjusted downwards.

Pediatric sensor(type reference 101A): Place the patient's index finger into the plastic sensor until it stops. The sensor cable should point towards the patient's hand.

The sensor should be oriented in such a way that the cable is positioned along the top of the hand.

Warnings**:**

1. Check the proper application of the sensor if pulse is recorded unreliably. The selected sensor location may be too thick, too thin, pigmented or coloured other way, as a result of the use of nail polish or cream, therefore it is inappropriate for proper light transmission If any of these situations occur, reposition the sensor.
2. The operator of the sensor is responsible for checking the compatibility of the monitor, sensor and cable. Incompatible components may result in degraded performance.
3. Improper application of the sensor may result in incorrect measurements.
4. Using under strong light exposure conditions may result in inaccurate measurements. In such cases, cover the sensor location with a tight fabric.
5. Intravascular dyes or externally applied colouring, such as nail polish or pigmented cream may lead to inaccurate measurements.
6. Sensor performance is affected by motion, therefore the use of the sensors is contraindicated for too active patients.
7. Do not fix the sensor to the place of use, because venous pulsation may result in inaccurate saturation measurements.
8. Apply the cable carefully in order to enable free patient movement and to avoid strangulation.
9. Do not use the sensor during MRI scanning. Conducted current may cause burns. Also, the sensor may affect the quality of the MRI image and the MRI unit may affect the measurement accuracy of the oximeter.
10. Do not check sensor accuracy by functional measuring meter (by oximeter simulator).
11. Don't apply non-invasive blood pressure monitor or any other equipment which may cause strangulation to the place of sensor location, as interrupted blood flow can result in the loss of pulse.
12. Do not transform or modify the sensor. Otherwise, the performance or accuracy of the sensors may be affected.
13. Do not disassemble or repair the sensors, as you lose warranty and it may result in product damage or injury. If you have any problem please contact qualified service personnel.
14. Disposal of the sensor must comply with local regulations.

Statement

1. Skin contacting sensor materials comply with EN ISO 10993 series standards
2. The pulse oximeter sensor is calibrated by the manufacturer before shipment
3. The sensor has been validated and tested in compliance with EN ISO 9919 2005 standard
4. The sensor has been validated and tested in compliance with EN IEC 60601-1-2 standard. For details, please refer to the section about electromagnetic emissions, electromagnetic immunity and the recommended separation distance between portable and mobile RF communications equipment and the sensors

Specifications
Peak wavelength: Red 660-666 nm, IR 895-920 nm
Maximum optical output power: 2mW
Measurement range: SpO_2 70% -100%
$A_{rms:}$ 80% - 100% $SpO_2 \pm 3\%$; 70% - 100% $SpO_2 \pm 4\%$;
Operating conditions: Temperature 10 – 40 °C; Relative humidity: 30%-75%
Storage conditions: Temperature -40 -70 °C; Relative humidity: $\leq$ 93%

13. Using a memory card

The apneABP recorder uses SD HC or MMC flash memory cards to record data during the monitoring session. Fully insert the Meditech supplied memory card into the recorder.

All data stored on the card will be erased during programming.

You will need a card reader unit built into or connected to your computer to transfer the recorded data to your database after a monitoring session. It is not possible to transfer such data using the optical interface cable, the only way is to remove the card from the recorder and insert it in a card reader unit. Use a USB 2.0 reader to transfer data to your PC. All data stored on the card when inserted into the recorder will be erased during programming the recorder. Please note that Meditech assumes no responsibility for the loss or destruction of such data. It is highly recommended to use a card exclusively for monitoring with one device; using the same card for other purposes may result in data loss, malfunction, or a failed monitoring session. Never remove the card, or remove the batteries from a card-based recorder while accessing the card (i.e., during storage, deletion or initialization operations), since data stored in the card may be destroyed. Remove the card from a recorder only if the monitoring session is completed. If you use a card from another source, or need to re-format the card supplied, note that according to Microsoft recommendations the SD card should be formatted for a FAT16 file system to work properly with Windows systems. apneABP will work with FAT32-formatted cards, but you may experience data access problems with cards formatted so on your computer. The memory card is a precision electronic device. Place it in the antistatic case provided when carrying and storing it. Failure to do so may result in damage to the card caused by static electricity. Do not apply strong force or impact to the card, nor bend or drop it. Do not put the card in the pocket of your pants, etc. Do not use or store the card in an environment with possibly strong static electricity/electric noise, including immediate proximity of mobile phones. Do not use or store the card in high temperature or humidity, nor subject it to a corrosive environment. Protect the contacts from dirt and particles that may come in contact with, or adhere to, the card. Use only dry, soft cloth to wipe away dirt. Keep the card out of the reach of children to prevent accidental ingestion. If the card is swallowed, seek medical assistance immediately.
The lifetime of the card is limited because it uses flash memory. It will not be able to save data after it has been used for a period exceeding its lifetime. In this case, replace the card with a new one.
Please note that as a security measure, postal department might subject all articles sent through mail to high level radiation. High level radiation erases all data stored on an SD card and renders the card useless. Please check and verify postal service policies before sending memory cards by mail.

14. Using CardioVisions software

The CardioVisions software package provides means to handle Meditech ambulatory blood pressure and ECG recorders. With CardioVisions it is possible to initialize (programme) a recorder, transfer (read) collected data from a recorder to your computer and analyze them. CardioVisions stores data transferred to the computer in its database for easy future access. The database offers user access control, organizing patient data in folders similar in appearance to those used for normal document storage, but with a high degree of safety for sensitive medical data. It also offers a comfortable archive-and-restore feature for a safe backup of large size recordings. Please create safety backups of your files and folders regularly, because this is the only way to restore data with this feature. CardioVisions provides detailed graphical and tabular displays of recorded data, a comprehensive set of editing features and full statistical analysis, all in a highly customizable user interface. Its efficient report generator and editor can create standard

reports automatically, but also allows for free editing of any report component like a word processor. In summary, CardioVisions lets you:

- manage (select, initialize and read data from) recorders
- browse patients and results of monitoring sessions in database
- view, edit and analyze data in a recording
- create, save and print a freely editable report.

Caution! Certain antivirus software programs can severely slow down CardioVisions. This can be avoided by adding the CardioVisions file formats as exceptions in the antivirus software. E.g.: *.ff2 and *.sm0 files.

CardioVisions editions and system requirements

Personal and Network Edition
CardioVisions comes in two different editions.
CardioVisions **Personal Edition** can be installed on a single computer and used only by one user at a time. Multiple users can work with one database in a computer network at the same time using CardioVisions **Network Edition**. This edition has to be installed on a server computer in a network, where users have access to CardioVisions over the network from the workstations. The use of the Network Edition requires registration.

Using Personal Edition for demo purposes
Demo data of ambulatory blood pressure monitors and ECG event recorders in CardioVisions Personal Edition are specifically included so that all features which would otherwise require registration will still work in an unregistered installation. There is no demo feature of CardioVisions Network Edition.

Computer requirements
CardioVisions can be installed on most Windows-based personal computers, but check before installation whether your computer meets the following requirements.

Minimum
CPU: 350 MHz Pentium II
RAM: 64 MB
VGA: 800*600 @ 16 bit colour
LAN: 10Mbit/s

Suggested
CPU: 2 GHz P4 or equivalent
RAM: 512 MB
VGA: 1024x768 @ 16 bit colour
LAN: 100 Mbit/s

HDD: about 40 MB for the software + disk space for database[2]
Operating system: Windows 98 SE / Me / 2000 / XP/ Windows 7

Please note that certain features of CardioVisions require a lot of calculations, so the faster your computer is, the shorter time you will need to have the analysis ready. Duration of data transfer depends on the card reader or, in case of Network Edition, the transfer speed of the computer network.

[2] The disk space necessary for the database depends on recorder type, number of patients and number of examinations. Typically, it takes 40-50 MB to store 1 apneABP recording. The installation of demo data requires about 200 MB.

Installation and first start

There are two very common errors that occur installing CardioVisions software.
- The default user is admin and this account is created with the installation. In order to use the device you must create a 'user' account. The Admin cannot access the recorder or patient data.
- Registration does not apply to apneABP monitors.

Installing CardioVisions Personal Edition

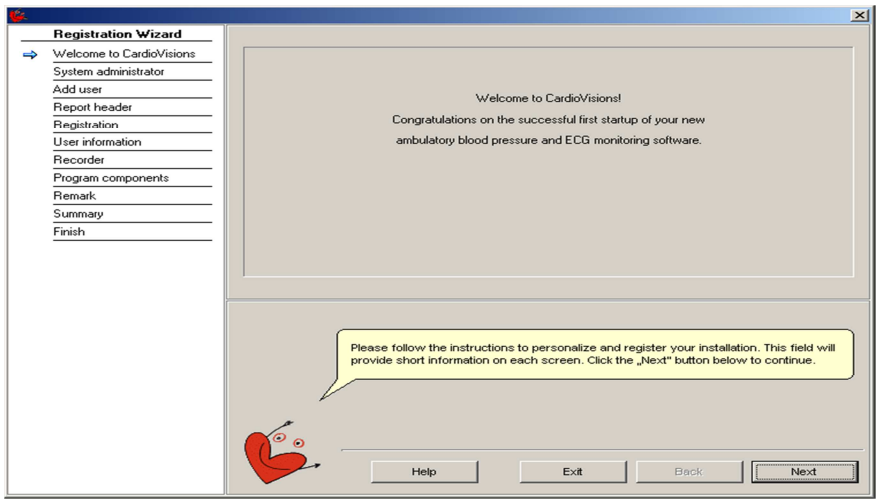
CardioVisions Personal Edition should be installed if you want to use the software on one PC or if you need demo data only. You need to go through the following steps:

- Select your preferred language
- Read and accept the License Agreement
- Choose components to install
  Here the installation of the USB driver is strongly advised.
- Choose recorder types you want to use
- Select the target folder of the installation
- Choose a Start menu folder for usual shortcuts.

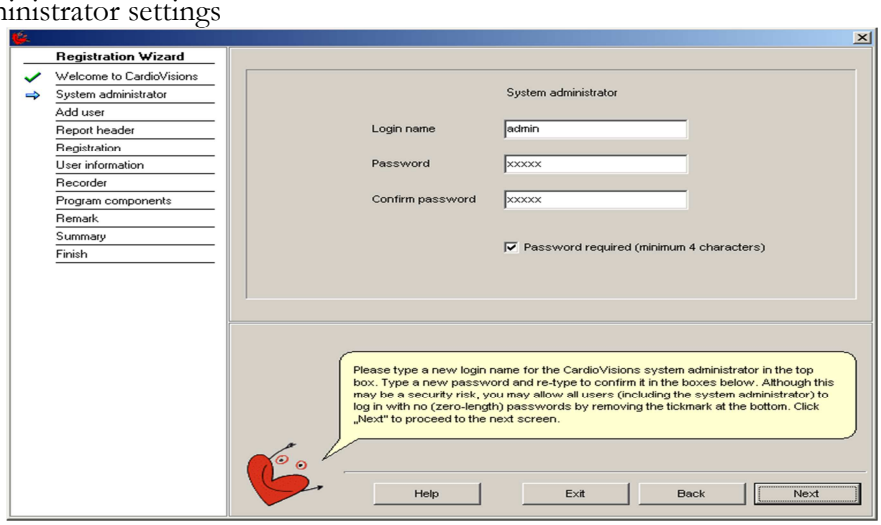
After finishing the installation, CardioVisions setup creates a startup icon on your desktop.

First start
You can start CardioVisions with the created shortcut on your desktop. At first you will be logged in as a system administrator (admin) who can start a registration, add new users or change data access levels. After the first start you will see the following screens:

Welcome screen

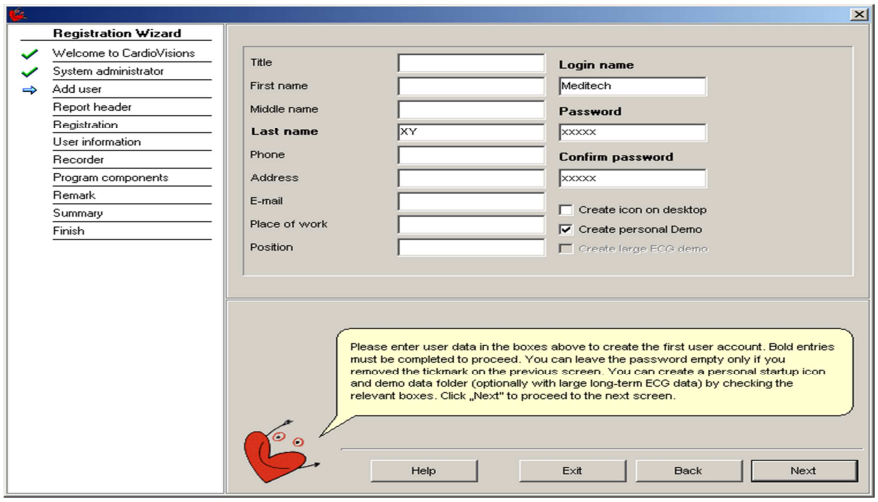


- System Administrator settings



Your default login name and password is **admin/admin.** Default settings can be modified here. Reminder: the system administrator cannot see medical data, as it is only the user who has access to measurements.

- Add a CardioVisions user



Here you are required to create a user account by filling in the empty spaces, but at least the bold entries. Creating a user is necessary to see medical data.

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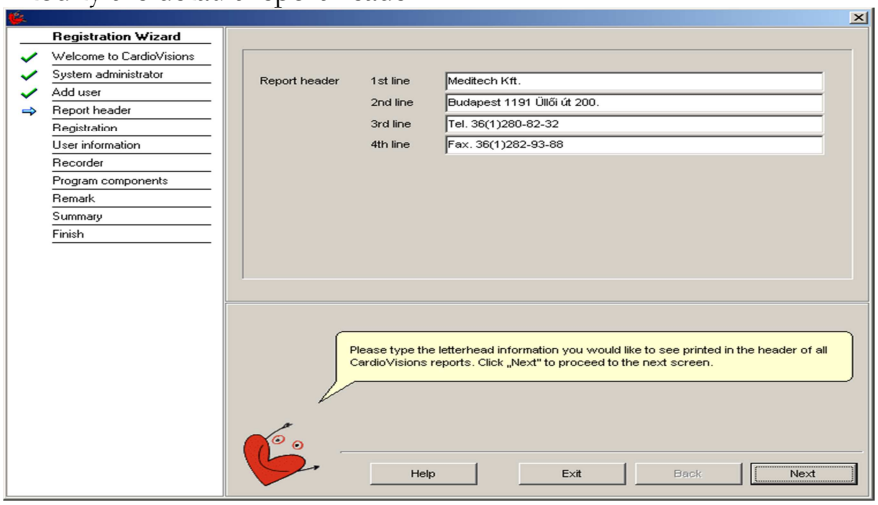
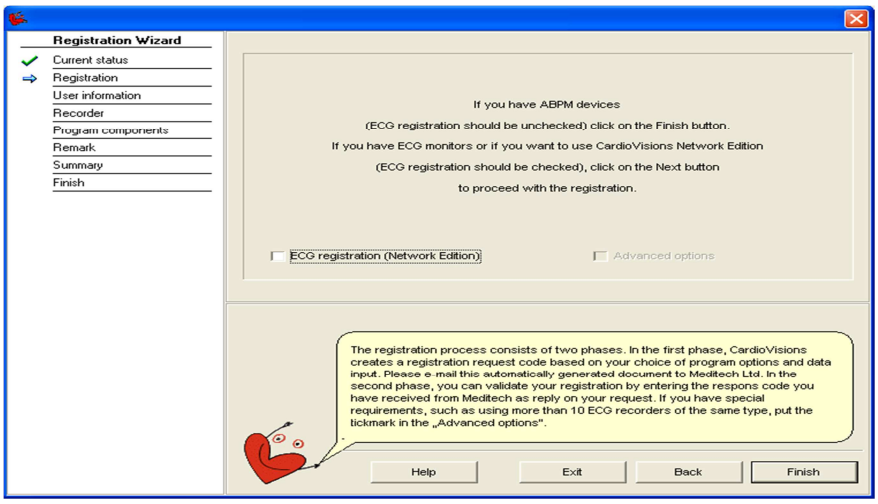
-

- Modify the default report header



In this screen you can change the report header data, which can be seen on the top of all printed report pages.

- Registration



Registration is not necessary for apneABP monitors. This function is for other devices only. You can quit and exit pushing the *'Finish'* button. If you want to make recordings, login as a User into the software.

Installing CardioVisions Network Edition

If you wish to access CardioVisions functions from several workstations in a computer network, you have to install CardioVisions Network Edition. The installation procedure looks quite similar to that of the Personal Edition (see above), but the result is quite different. While Personal Edition setup installs a typical program where you have a single executable file to start and then you can access all functions, the Network Edition setup will install two separate applications, two executable files: one for the networked CardioVisions database engine application (also called the database server), and another for the so-called CardioVisions client application, i.e., the user-end of the program to ask for data over the network from the database engine on any workstation. Therefore, the Network Edition has to be installed on a properly configured server computer. After the installation, the CardioVisions database engine will be automatically started by default whenever the server computer is started. The Network Edition has to be installed on the server computer, on the individual workstations only a shortcut has to be created. Then, as a result, the database engine will run on the server computer continuously, and the CardioVisions client can be started on any workstation with a proper shortcut (startup icon). For all normal user purposes, the CardioVisions client of the Network Edition is indistinguishable from the program used in the Personal Edition. There is one important difference in behaviour, however: if you use the Network Edition and the server computer is shut down, it will not be possible to start CardioVisions from the workstations. Similarly, even if the server computer is switched on, but the CardioVisions database engine is not running (it is stopped, shut down or not started at all), it will be impossible to use CardioVisions.

Compared to the installation of CardioVisions Personal Edition, there is one additional step to take during the installation of the Network Edition. After you have chosen the recorder type(s) to use, you are asked to select an IP-address (a network property) through which the database engine can communicate with the client(s) running on any workstation. This is a question only if the server has multiple network adaptors, either for intra- or extranet purposes, or because of different physical subnets.

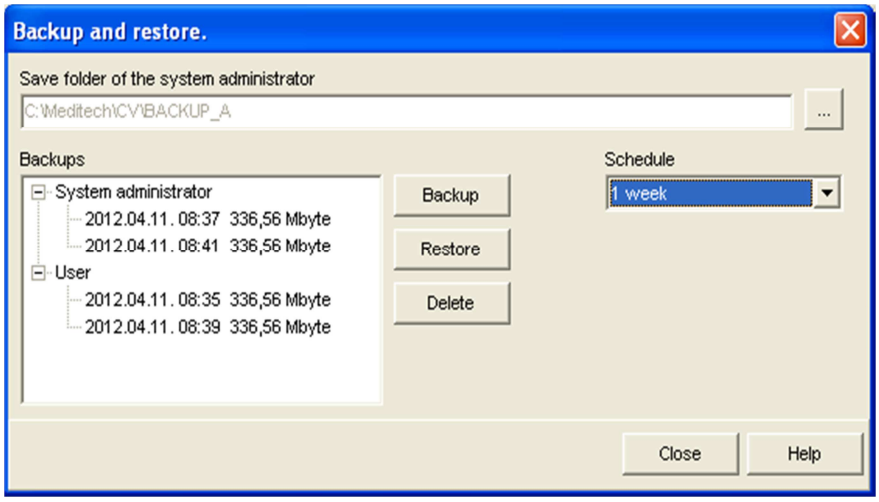
To complete your CardioVisions Network Edition installation, you have to manually share the "CLIENT" folder of your installation with read-only access from all workstations and you have to create a shortcut on each workstation pointing to the CardioVisions client application executable file in this folder (its name is CV001.EXE). This is best done manually as automatic sharing is either impossible or can have serious security risks, and once the shortcut is created, you can simply "copy-paste" it to all workstations where you want to use CardioVisions. If you have any doubt, consult your computer network administrator.

It is possible to configure your own CardioVisions database engine application to use different options in the unlikely case of networking problems. Since database engine is an auto-configuring application, change a working configuration only if it is absolutely necessary and always with the close assistance of an experienced network specialist. To change database engine configuration, first request all users to log out from CardioVisions and close all CardioVisions clients on all workstations, then bring up the database engine application from the system tray on the server computer by double-clicking its icon, then choose Server – Stop, then select the required command of the Config menu. After your changes, choose Server – Start to make the CardioVisions database engine services available to users again.

Backup

Creating a backup from CardioVisions database is strongly recommended to prevent data loss. It is advised to create a backup often, monthly, weekly or even daily depending on the frequency of the software usage.

The function is available both for the User (Tools/Backup) and for the System Administrator (Tools/System administrator tools/Backup and restore). While the former can create backups only manually, the latter has the possibility to create backups both manually and automatically according to preset intervals.



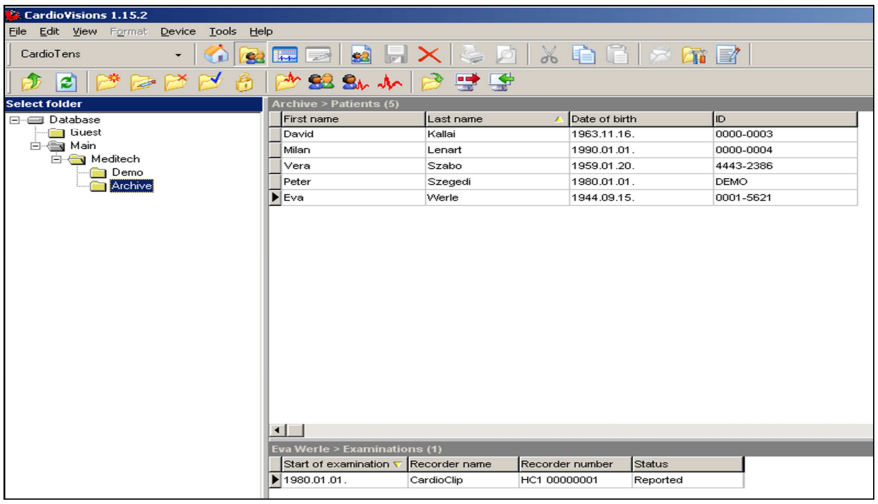
The User's backups, from which only the last two can be stored, are saved into C:\Meditech\CV\Backup_U, while the System Administrator's backups, the number of which is unlimited, are saved into C:\Meditech\CV\Backup_A.

Automatic backup can be made weekly, fortnightly or monthly. If the function is selected the backup will automatically be done compared to the last backup in the preset schedule.

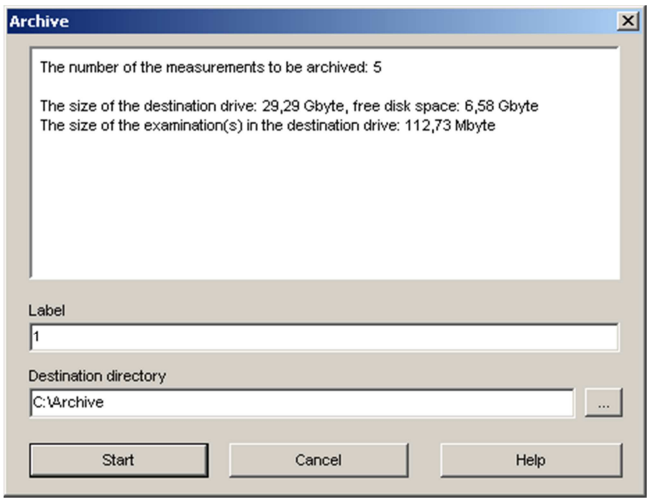
Archiving

CardioVisions data archiving refers to the long-term storage of the large-size recordings in order to free up space in the database. Archiving can be done either by the User or the system administrator. The process is the following:

1.) Enter the software and select the Database icon ().
2.) Create a new folder into which you can collect the selected examinations which have to be archived.



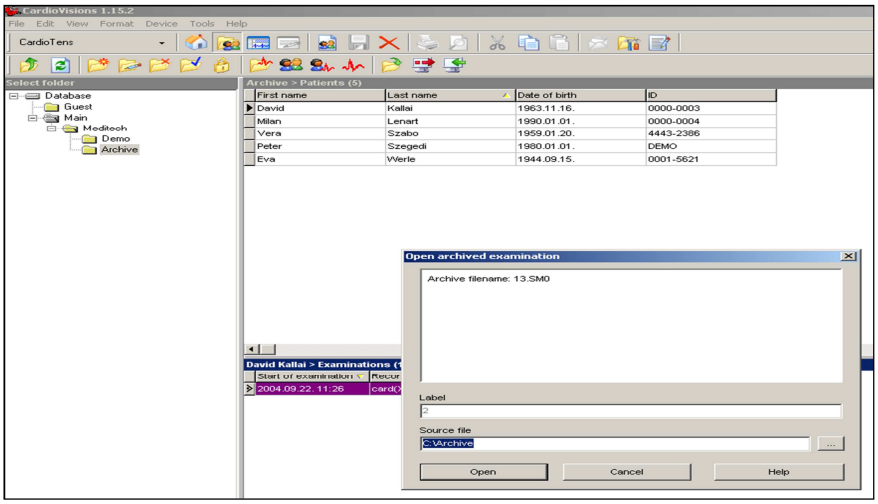
3.) After clicking 'Tools/Archive examinations from the selected folder', a new panel will appear on your screen, which will inform you about the number and the size of the measurements in the folder and the size of your destination drive.



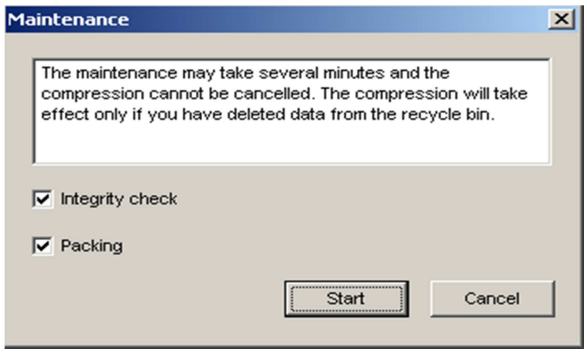
Select the folder in the destination directory in which you want the examinations to be saved. You should type in or select the name of the destination directory to archive to the hard disc.

4.) If you have made sure that the size of the data to be archived does not exceed the size of the free space on the destination drive you can start the process. The speed and the duration of the process depend on the size of the recordings.
5.) When the process is completed, a message window will notify you about it. Click the 'Close' button to exit the window. The archived examinations will be coloured purple in your database. To open the examination like this, the program will ask the destination route of the archived data. If you have saved the data on the hard disc, just simply select the source file.

After archiving your files to a PC, you can copy data to a CD or DVD as well. If you choose this solution, write the name of the disc into the 'Label' field in order you can open the archived files easily later. If you want to have access to your archived files, place the disc in the drive with the appropriate label then select the source file.



6.) If you have started archiving to free up space in your database, enter the software as a system administrator and click 'Tools/ System administrator's tools/Maintenance'. Using this command will compress your database. Put a tickmark next to 'Integrity' to make sure that your database does not contain any injured data. Put a tickmark next to 'Packing' to create a smaller database. Note, please, that the process will require at least as much free space as the size of your database.



15. Meditech product warranty information

(a) RECORDER WARRANTY. The main recorder unit will be free from defects in materials and workmanship under normal use and service for a period of two (2) years from the date of receipt. This warranty covers the recorder unit only. This warranty does not cover any accessories that might come with the recorder unit.
(b) ACCESSORIES WARRANTY. The non-disposable accessories delivered with the recorder unit will be free from defects in materials and workmanship under normal use and service for a period of one (1) year from the date of receipt. This warranty does not cover disposable accessories, packaging materials, accumulators and batteries, cuffs, or any of their components.
(c) CUFF WARRANTY. The cuff(s) - if delivered with a recorder unit - will be free from defects in materials and workmanship under normal use and service for a period of six (6) months from the date of receipt. This warranty covers the cuff(s) delivered with a recorder unit exclusively.
(d) SOFTWARE WARRANTY. The CardioVisions software under normal use will perform substantially in accordance with the accompanying written/electronic documents for a period of ninety (90) days from the date of receipt.

This warranty is valid at the representative address of Meditech Ltd. unless otherwise displayed upon a commercial invoice or any other valid business document duly signed by the supplier and the recipient of the Meditech product. If such business document displaying a certain site for warranty validity cannot be presented, this warranty is valid at Meditech HQ office in Budapest, Hungary. This warranty does not cover any malfunction or defects of the recorder unit or any of its accessories arising from improper use, the use of inadequate accessories, accident, theft, or use of the recorder unit outside its operating environmental specifications and intended measurement range. Warranty conditions do not apply to putative defects that are considered to be defects by the Partner due to inadequate knowledge or improper use of the products. Products returned with such putative defects are subject to service checkup charge. Removing the closing label from the back side of the recorder unit, or opening the unit any other way voids this warranty.

Exclusion of biohazard. Meditech will not accept for repair potentially infectious products or accessories, especially pouches and cuffs that might have been in direct contact with the patient, and could not be, or (potentially) were not, properly disinfected, even within the warranty period. If a problem occurs within the warranty period, such accessories will be replaced without any physical inspection, reserving the rights to hold an inspection when found necessary.

No other warranties. Meditech disclaims all other warranties, expressed or implied, including, but not limited to, implied warranties of merchantability and fitness for a particular purpose, with regard to the recorder unit, any accessory or other accompanying hardware, and the software.

No liability for consequential damages. In no event shall Meditech be liable for any special, incidental, indirect, or consequential damages whatsoever (including, without limitation, damages for loss of business profits, business interruption, loss of business information, loss of data, or any other pecuniary loss) arising out of the use of or inability to use the recorder unit, its accessories and/or the CardioVisions software, even if Meditech has been advised of the possibility of such damages.

16. CardioVisions software license agreement

Important – read carefully: This License Agreement is a legal agreement between you (either an individual or a single legal entity) and Meditech Ltd. for the CardioVisions software, which includes computer software (SOFTWARE) and may contain accompanying data carrier, printed material and 'on-line' or electronic documentation. By installing, copying, or otherwise using the SOFTWARE, you agree to be bound by the terms and all the information and conditions described in this Agreement. If you do not agree to the terms of this Agreement, promptly return the unused SOFTWARE to the place from which you obtained it.

Software license: The SOFTWARE is protected by copyright laws and international copyright treaties, as well as other intellectual property laws and treaties. The SOFTWARE is licensed, not sold.

Grant of license: This Agreement grants you the following rights:

Software: You may install and use one copy of the SOFTWARE only on one computer.

Storage/Network Use: You may also store or install a copy of the SOFTWARE on a storage device, such as a network server, used only to install or run the SOFTWARE on your other computers over an internal network.

Description of other rights and limitations

Limitations on Reverse Engineering, Decompilation, and Disassembly: You may not reverse engineer, decompile, or disassemble the SOFTWARE.

Separation of Components: The SOFTWARE is licensed as a single product. Its component parts may not be separated for any purposes.

Rental: You may not rent or lease the SOFTWARE from anyone except from Meditech or an authorized representative of Meditech.

Demonstration: You may only demonstrate SOFTWARE if all the information described in this Agreement is disclosed to third parties.

Software Transfer: You may not transfer any of your rights under this Agreement, to any other party, without the prior written consent of Meditech Ltd.

Termination: Without prejudice to any other rights, Meditech may terminate this Agreement if you fail to comply with the terms and conditions of this Agreement. If such event occurs, you must destroy all copies of the SOFTWARE and all of its components.

Copyright

All title and copyrights in and to the SOFTWARE, the accompanying electronic and printed materials, and any copies of the SOFTWARE are owned by Meditech Ltd. The SOFTWARE is protected by copyright laws and international treaty provisions, therefore, you must treat the SOFTWARE like any other copyrighted material, except that you are allowed to make a copy of the software only for control and evaluation purposes. You may not copy the printed materials accompanying the SOFTWARE.

Miscellaneous
This Agreement is governed by the laws of Hungary. Should you have any questions concerning this Agreement, please contact Meditech Ltd.

Limited warranty
Meditech Ltd. guarantees, that (a) the SOFTWARE under normal use will perform substantially in accordance with the accompanying written/electronic documents for a period of ninety (90) days, and all supplementary hardware will be free from defects in materials and workmanship under normal use for one (1) year from the date of receipt.

No other warranties. Meditech disclaims all other warranties, either expressed or implified, including, but not limited to, implied warranties of merchantability and fitted for a particular purpose, with regard to the recorder unit, any accessory or other accompanying hardware and the CardioVisions software.

No liability for consequential damages. In no event shall Meditech be liable for any special, incidental, indirect, or consequential damages whatsoever (including, without limitation, damages for loss of business profits, business interruption, loss of business information, loss of data, or any other pecuniary loss) arising out of the use, or inability to use this product, even if Meditech has been advised of the possibility of such damages.

17. EMC information

Medical electrical equipment should be used with precautions according to EMC, and must be installed according to the EMC notices disclosed in this manual as mobile RF transceivers could adversely affect it.

Electromagnetic emission

Meditech monitors are suitable for use in the specified electromagnetic environment. The purchaser or user of the device should assure that they are used in an electromagnetic environment as described below.

Emission test	Compliance	Electromagnetic environment
Radiated and conducted RF emission CISPR 11	Group 1	Meditech devices use RF energy only for their internal function. Therefore, the emission is very low and it is not likely to cause any interference in nearby electronic equipment.
Radiated and conducted RF emission CISPR 11	Class B	Meditech devices are suitable for use in domestic establishments and in establishments directly connected to the low voltage power supply network which supplies buildings used for domestic use.
Harmonic emission IEC61000-3-2	Not applicable	---
Voltage fluctuations/ Flickers IEC61000-3-3	Complies	Meditech devices are suitable for use in establishments directly connected to a public low voltage mains network.

Electromagnetic immunity

The apneABP device is suitable for use in the specified electromagnetic environment. The purchaser or user of the product should assure that they are used in an electromagnetic environment as described below.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6KV contact +/- 8 KV air	+/- 6KV contact +/- 8 KV air	Floors are wood, concrete or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
Electrical fast transient/burst IEC 61000-4-4	+/- 2KV for power supply +/- 1KV input/output lines	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	+/- 1KV differential mode +/- 2KV common mode	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip) for 0.5 cycle; 40% UT (60% dip) for 5 cycles; 70% UT (30% dip) for 25 cycles; <5% UT (>95% dip) for 5 sec.	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment. If the user of Meditech ambulatory blood pressure monitors requires CLINICAL UTILITY during power mains interruptions, it is recommended that parts of the Meditech ABPM-05 system where applicable be powered from an uninterruptible power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical commercial and/or hospital environment.

Note: U_T is the nominal voltage of mains.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment
Conducted RF IEC 6100-4-6	3V eff 150KHz-80MHz	Not applicable	Portable and mobile RF communications equipment are used no closer to any part of Meditech apneABP, including cables, than the Recommended Separation Distance calculated the formula written below. Recommended Separation distance: $d=[3,5/V1]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80MHz-2,5GHz	3V/m	$d=[3,5/3V/m]\sqrt{P}$; (80MHz – 800MHz) $d=[7/3V/m]\sqrt{P}$; (800MHz – 2,5GHz) where: P is the highest radiated power disclosed by the manufacturer of transmitter [W]; d is the recommended separation distance [m].

1. Note: in case of frequency 80MHz or 800 Mhz, the formula for the higher range is applicable.
2. Note: these are guidelines. Actual conditions may vary.

Recommended separation distance

Meditech ambulatory blood pressure and pulse oximeter monitors are intended to be used in electromagnetic environment with controlled RF disturbances. The purchaser or user of the devices may help to reduce electromagnetic disturbances by defining the separation distance between the transportable or mobile RF telecommunication equipment (transmitters) and the device, depending on the highest output power of the telecommunication equipment.

	Separation distance in function of the frequency of the transmitter (m)		
The highest output power of the transmitter (W)	**150KHz-80MHz d=(3,5/V1)√P**	**80MHz-800MHz d=(3,5/E1)√P**	**800MHz-2,5GHz d=(7/E1)√P**
0,01	Not applicable	0,12	0,23
0,1	Not applicable	0,38	0,73
1	Not applicable	1,2	2,3
10	Not applicable	3,8	7,3
100	Not applicable	12	23

If this table does not contain the highest output power of the transmitter, the d separation distance [m] can be calculated by the formula, depending on the frequency of the transmitter, where P is the rated highest output power of the transmitter [W].

1. Note: in case of frequency 80MHz or 800 MHz, the formula for the higher range is applicable.
2. Note: These are guidelines. Actual conditions may vary.